

EXHIBIT 17

Daily Mail

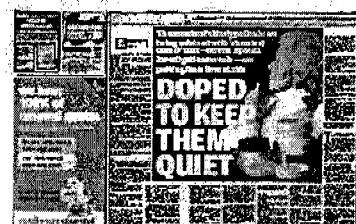
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Thousands of elderly patients are being subdued with 'chemical coshes' that – as this Special Investigation reveals – are putting their lives at risk

DOPED TO KEEP THEM QUIET



Picture: GETTY Posed by model



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**By JEROME
BURNE**

WHEN Shirley Newrock was in her early 40s, her family suffered the sort of human tragedy common to many families throughout the country.

At the age of just 55, her husband Michael, whose behaviour had become increasingly erratic, was diagnosed with Alzheimer's. The couple had three teenage children living at home at the time and Shirley had recently gone back to work as an illustrator of children's books.

'Michael was a GP, the senior partner in a local practice, but soon he couldn't work and I had to give up my job to look after him,' Shirley says. 'Most people with the disease are old and rather frail, but he was still strong and otherwise healthy.'

'It made looking after him much harder especially when he developed a form of agitation which meant he couldn't sit still for any length of time.'

'He would spend hours pacing up and down or going on long walks; he'd get furious when we had to bring him back to the house.'

Difficult as their situation was, Shirley still felt positive. 'Even though Michael was on edge and terribly restless, we could still talk to him,' she says. That changed when their GP tried to help control Michael's symptoms, prescribing him an anti-psychotic drug.

'Within days he appeared not to understand anything,' says Shirley. 'He started twitching; his face became like a mask. When I complained, they upped the dose and it got worse.'

'Then they put him on a different anti-psychotic drug and he began drooling and walking all crooked, bent over on one side. It was terrible and it all happened so quickly.'

'Three months before he'd been a strong man walking around the park, but now he needed a walking frame to get to the lavatory. His memory and his speech were gone. He lived for another 11 years, but I've since discovered that it's quite likely that it was the drugs that made him decline so fast at the beginning.'

'Michael died three years ago, but I still shudder when I think about what those drugs did to him.'

Anti-psychotic drugs were originally developed for treating schizophrenia. They act like heavy tranquillisers, 'calming down' patients by, for instance, making their hallucinations less intense. The theory is that they do the same for patients with dementia.

Around 750,000 people in the UK have dementia; half of them have the most familiar type, Alzheimer's disease.

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YMPOMS include memory loss, confusion, poor concentration, as well as delusions and hallucinations. There's no 'cure', so doctors are left scrabbling for anything that may help — which is why anti-psychotics come into the picture.

But a Good Health investigation has found that leading dementia experts are extremely concerned by the use of these drugs. Not only are anti-psychotics being widely misused, they say, but recent research also shows that these drugs have deadly side-effects, and are no better than a placebo for relieving patients' symptoms.

'These drugs are massively over-prescribed to patients with dementia,' says Stephen Jackson, professor of clinical gerontology at King's College, London.

'They are very strong tranquillisers, licensed to treat psychosis, and they can have very serious side-effects. They should be avoided unless absolutely necessary.'

Anti-psychotics are known to have adverse effects such as shuffling gait, extreme tiredness and a worsening of memory and concentration. But more serious side-effects have emerged. Some brands have now been found to double — even triple — the risk of a stroke among the elderly.

Two years ago, the government medicines watchdog the MHRA specifically warned doctors against using two of the most popular ones on dementia patients because of this risk.

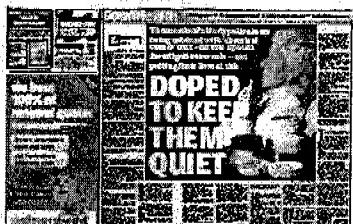
Then, last year, the U.S. Federal Drugs Agency ordered that warnings

be put on the packaging after dementia patients were found to be nearly twice as likely to die of pneumonia or cardiovascular problems.

Earlier this month Eli Lilly, the American manufacturer of Zyprexa, the top-selling anti-psychotic, paid out an astonishing £259 million to settle claims that it hadn't given adequate warning of other side-effects, which could lead to diabetes.

So anti-psychotics don't sound like the sort of drug you would want to be given to your frail, elderly relation. Yet despite these clear risks and warnings, our investigation has found that every year in Britain these drugs are prescribed to nearly 200,000 dementia patients both in care homes and living at home.

'It is a crazy situation,' says Dr Clive Ballard, director of research at the Alzheimer's Society. 'Anti-psychotics should be used only in an emergency to help a patient who's in a very agitated or distressed state. They are



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in no way a treatment for dementia, and they should almost never be used on a regular basis.'

These drugs effectively act as a chemical cosh. Indeed, rather than helping patients with their behaviour, many carers report that the drugs actually make them much more confused.

What makes their widespread use even more extraordinary is the fact that they are not officially approved to treat dementia.

And the cost to the NHS of these unlicensed, ineffective and dangerous drugs? Just treating dementia costs around £70 million a year — a huge amount of money when healthcare for the elderly is already known to be underfunded.

It is, says Professor Jackson, a 'stupendous waste'.

There are two types of anti-psychotic drugs. The originals, first used in the 1950s, caused uncontrolled muscle movement and

spasms. Patients would drool, have tremors, grimace and twitch.

About ten years ago an improved version, known as 'atypicals', were introduced, and until very recently most experts believed they were more effective and had fewer side-effects. Between 1999 and 2004 their use soared, with prescriptions for the elderly (aged over 60) increasing by 400 per cent in the UK.

However, recent research shows that the newer drugs are hardly an improvement. Three major studies by government-funded independent bodies in both the UK and the U.S. — involving nearly 2,000 patients — have all found that the newer 'atypicals' are effectively no better than their predecessors, either in terms of the quality of life they allow patients or the side-effects they cause.

Both new and old versions are prescribed to dementia patients 'off label'. This means the MHRA

has not licensed them for use in treating dementia, so there is no evidence supporting their use.

HOWEVER, doctors are allowed to prescribe the drugs if, in their judgement, they will help patients. The doctor then takes personal responsibility for the decision.

But should doctors continue doing this, now the evidence is so strong that the current anti-psychotics are neither safe nor effective, and are no better than older drugs?

The MHRA has issued two warning about anti-psychotics. First, in 2002, it warned that atypi-

cals could adversely affect blood glucose levels, making diabetes type-problems more likely.

Then, in 2004, the agency advised all doctors that the two best-selling brands — Zyprexa and Risperidol — should 'not be used for the behavioural symptoms of dementia' because of the increased risk of stroke.

However, it is clear from answers to Parliamentary questions that the warnings had little effect in the UK. The number of prescriptions to all patients aged over 60 for Zyprexa, the most widely used atypical, dipped from 460,000 in 2004 to 420,000 in 2005 — a drop of less than 10 per cent.

Dr Ballard estimates that only about 20 per cent of the atypicals given to the over-60s are for the licensed use of schizophrenia or manic-depressive disorder. The rest are largely prescribed for dementia.

Doctors have continued using the drugs because they have nothing else and because they believe the drugs may help to improve the

behaviour of some patients. However, four months ago research published in the respected New England Journal of Medicine found no basis for these claims either.

A double-blind trial tested the effectiveness of several anti-psychotics (including Zyprexa and Risperidol) in treating behaviour in dementia patients and found little difference between the drugs and placebo.

The researchers concluded that the marginal effect, plus the risk of death and other side-effects, made atypicals not worth using.

'These medications are not the answer,' said Dr Thomas Insel, director of the American National Institute of Mental Health, which funded the study.

But, given this evidence, how could doctors have got it so wrong?

Dr Peter Jones, of the Department of Psychiatry Cambridge University, who conducted the recent UK study showing very little differ-

ence between old and new anti-psychotics, said: 'The claims of superiority for the newer drugs were greatly exaggerated.'

'Aggressive marketing of these drugs may have contributed to this enhanced perception of their effectiveness.'

It's also been suggested that the drug companies have been less forthright about unfavourable trial results.

'We learned about an increased risk of stroke for dementia patients with these drugs only after the MHRA had analysed both pub-

lished and unpublished trials,' says Dr Ballard. 'The published material wasn't telling the full story. The drug companies have definitely attempted to paint a rosier picture than is really the case.'

Internal company documents that formed part of legal proceedings against Eli Lilly seem to indicate the company downplayed the side-effects involving weight gain and raised blood sugar levels.

THE company says it has given all appropriate data to the U.S. drug regulator, and claims the documents have been taken out of context. But as well as agreeing the £259 million out-of-court settlement over labelling earlier this month, the company also paid out £362 million in June last year to settle more than 8,000 similar claims.

Its chief executive Sidney Laurel said: 'While we remain confident that these claims are without merit, we wanted to reduce significant uncertainties involved in litigating such complex cases.'

So what relevance does all this have for families worried about an elderly relative with dementia?

The concern is not so much the side-effects of weight gain, says Professor Ballard. 'Many of my patients are losing weight,' he says.

However, he says raised blood sugar levels caused by drugs known to be linked to stroke are worrying.

What is more, the sheer scale of the American claims — 26,000 cases — must raise concerns about how fully such side-effects are being officially reported in the UK.

The MHRA said last week that it had only received a total of 175 reports linking Zyprexa with raised blood sugar levels or diabetes, and 140 associated with weight gain.

A spokesman for Eli Lilly told Good Health: 'Patient safety is our top priority. While Zyprexa is not licensed to treat elderly patients with dementia, we are aware that anti-psychotic agents, such as Zyprexa, are sometimes prescribed to elderly patients who have dementia-related psychosis. Therefore it is important that healthcare professionals be kept fully informed of label changes.'

'Consistent with Lilly's policy of full disclosure, warnings about safety have been updated throughout the life of the medicine.'

■ *SOME of the names in this article have been changed.*

